

Chairman Tom Davis
Committee on Government Reform
Opening Statement
“The Regulation of Dietary Supplements: A Review of Consumer Safeguards”
March 9, 2006

Good morning and welcome to today’s Government Reform Committee hearing on dietary supplements.

A little more than a year ago, the Committee launched a bipartisan investigation into the use of steroids and performance-enhancing drugs in Major League Baseball and other professional sports. One of the results of that investigation was baseball’s adoption of stricter penalties for steroid use and new penalties for the use of illegal stimulants.

But our steroids inquiry also led us in directions we had not anticipated, and that’s one reason we find ourselves here today, taking a closer look at the massive and fast-growing dietary supplement industry.

By some recent estimates, dietary supplements are a \$20 *billion* a year industry. The Food and Drug Administration counts 29,000 dietary supplements on the market today, up nearly 20 percent from a decade ago. A 2004 government survey showed nearly 60 percent of Americans take dietary supplements regularly.

Despite the vast size of this industry and the obvious popularity of supplements with American consumers, I fear that there remains great – and potentially dangerous – confusion over how closely the government regulates these supplements. Consumers mistakenly believe supplements are regulated like pharmaceutical drugs, but that is simply not the case.

For example, according to a 2002 Harris Poll survey, 68 percent of American adults believe the federal government requires supplements to carry warning labels about potential side effects.

Not true.

The poll showed 59 percent of people believe supplements must be approved by a government agency, like the Food and Drug Administration, before they can be sold.

Not true.

And, 55 percent of people believe supplement manufacturers were not permitted to make claims regarding safety without solid scientific evidence.

Again, not true.

Today, we are here to learn the facts about the exact responsibility of the federal government in regulating dietary supplements. And what role is played by independent groups such as NSF International, U.S. Pharmacopeia, and Consumerlab.com., who either independently test supplements or will certify supplements on behalf of the manufacturers.

And just as important, we want to understand how this information is conveyed – if at all – to the consumer. We have millions of Americans buying products, many under the false assumption that the items have been approved for use by the FDA.

Are all supplements dangerous? Hardly. But are all of them perfectly safe for everyone to take? Of course not. Just look at ephedra. The FDA in 2004 banned its use in dietary supplements, citing concerns over its cardiovascular effects, including increased blood pressure and irregular heart rhythm. The action was spurred in part by the death of Baltimore Orioles pitcher Steve Belcher, who had been taking ephedra. But for years there was concern, even at the FDA, that ephedra was dangerous.

Ephedra and its variants were the first dietary supplement banned for sale by the FDA under the 1994 Dietary Supplement Health and Education Act, known as DSHEA (Da-SHAY). Under this law, dietary supplement manufacturers do not need FDA approval before manufacturing, labeling, distributing, and marketing their products. FDA's regulation of dietary supplements is primarily a post-market program. For supplements that do not contain a new dietary ingredient – that is, a dietary ingredient that was not sold in the United States before October 15, 1994 – there is no requirement for manufacturers to provide FDA with evidence about the safety of the product either before or after marketing.

While DSHEA does require manufacturers to label their product as a “supplement” and include a full list of ingredients, manufacturers are not required to alert FDA to adverse event reports they may receive from consumers. Furthermore the law requires FDA to prove “a significant and unreasonable risk to health” before a dietary supplement can be removed from the shelves.

In some cases, the regulatory gaps in the law have been filled by the private sector. Our second panel witnesses today will explain how their organizations test supplements and in some cases certify that the manufacturer is accurately listing the ingredients on the label.

One of these groups, NSF International, helped create national packaging standards for supplements and now works with the NFL and Major League Baseball to certify that supplements do not contain banned substances such as performance-enhancing drugs.

I find this telling – that millionaire athletes, with top-notch athletic trainers on staff, need to resort to a third party to let them know which supplements are safe to take and which are not, because they might unexpectedly (and illegally) contain performance-

enhancing drugs. What is the average consumer to do? How many of those 29,000 supplements really contain what they claim? How many truly have an exhaustive list of all ingredients on their labels?

The *Washington Post* highlighted this problem in an October 18, 2005 article, for which the newspaper purchased five dietary supplements, all labeled as muscle builders and all available over the Internet, and had them tested by the UCLA Olympic Analytical Laboratory for anabolic steroids. All five tested positive for what are commonly known as “designer steroids.”

Moreover, just two weeks ago, the FDA announced that \$3 million worth of products containing ephedrine alkaloids were seized from Hi-Tech Pharmaceuticals, a Georgia company that was manufacturing and selling three dietary supplements containing the banned substance.

I hope today’s hearing will be able to shed more light on this enormous industry, and that we learn a bit more about how consumers can protect themselves. We will start our discussion with a panel of witnesses from the three federal agencies that exercise some jurisdiction over this field – the FDA, the National Institutes of Health and the Federal Trade Commission, and I very much look forward to hearing their testimony, as well as that of our second panel.